Opening Statement of the Honorable Fred Upton
Subcommittee on Health
Markup on "H.R. 1407 and a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain"
May 7, 2013

(As Prepared for Delivery)

Today we will consider important bipartisan legislation to reauthorize the animal drug user fees and secure our nation's prescription drug supply chain.

First, we will mark up H.R. 1407, the Animal Drug User Fee Amendments of 2013, which would reauthorize the Animal Drug User Fee Act (ADUFA). The Amendment in the Nature of a Substitute to H.R. 1407 would simply add the language of H.R. 1408, a bill to reauthorize the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA), to the bill.

The American people have benefited greatly because of ADUFA and AGDUFA, ensuring that veterinarians, livestock and poultry producers, and pet owners have access to the drugs they need to keep their animals healthy. The programs have also assisted animal drug manufacturers by creating a stable and predictable FDA review process, and they have helped in keeping the American food supply safe.

Reauthorization is critically important for companies like Zoetis, which employs over 700 folks in southwest Michigan, as these programs provide the predictability they need to help them produce innovative drugs for pets and livestock.

Today we'll also mark up the bipartisan discussion draft on securing the prescription drug supply chain. This draft would work to protect American families against counterfeit drugs while eliminating hundreds of millions of dollars worth of duplicative government red tape saddling American drug manufacturers, wholesale distributors, and pharmacies.

We have worked on this issue on a bipartisan basis for over a year. Last March, we held a hearing on securing the supply chain as part of our reauthorization of the Prescription Drug User Fee Act (PDUFA). Our discussions continued during the PDUFA negotiations with our colleagues in the Senate and throughout the remainder of the Congress. Unfortunately, we did not get it done last Congress, but it is my hope that we will have a bill on the president's desk by the August recess.

We have also sought input from stakeholders like Pfizer and Perrigo in Michigan, as well as our small pharmacies. This hard work is evident in the legislative product we will consider today.

This subcommittee held a productive hearing on the discussion draft on April 25, and last Friday, we released a new discussion draft which would require manufacturers to pass transaction statements starting in January 2015 and phase-in that requirement for wholesale distributors and pharmacies. This will bring real security to the supply chain in just a couple years.

The draft also would set forth a collaborative process so the FDA and supply chain stakeholders could work together in an effort to better understand how to move to unit-level traceability. Finally, it would require FDA to take what it learns from that collaborative process and issue a proposed regulation on unit-level traceability in 2027. When it issues this regulation, FDA would have to take steps to ensure that small pharmacies are not overly burdened.

This markup is an important step in finishing the bipartisan work on securing the prescription drug supply chain that we began well over a year ago.

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